TABLE 3.1: Sample (Tabular) Adverse Event Outcome Report. (cont'd)

Agency Name: Faircare Home Health Services
Agency ID: HHA01
Location: Anytown, USA
Medicare Number: 007001
Medicaid Number: 999888001

Requested Current Period: 09/1999-08/2000
Actual Current Period: 09/1999-08/2000
Number of Cases in Current Period: 601
Number of Cases in Reference Sample: 29983
Date Report Printed: 11/30/2000

Adverse Event Outcome Report
Patient Listing

Development of Urinary Tract Infection

Complete Data Cases: 399 Number of Events: 8 Agency Incidence: 2.0% Reference Incidence: 1.1%

Patient ID	Last Name	First Name	Gender	Birth Date	SOC/ROC	DC/Transfer
859294045	Dunn	Jim	M	10/17/1920	11/20/99	12/19/99
565570409	Rosling	Walter	M	10/21/1938	05/26/00	08/13/00
014760252	Connelly	Sherwood	M	11/14/1940	07/29/00	08/30/00
472551333	Guinn	Rosemary	F	08/18/1915	03/17/00	03/26/00
773642368	Mullins	Caleb	M	01/23/1938	10/19/99	01/20/00
759333066	Beck	Jan	F	07/04/1929	07/25/00	07/30/00
136056137	Hayes	Edd	M	10/05/1929	05/07/00	05/07/00
947917397	St. Germain	Teri	F	11/29/1940	06/17/00	07/18/00

Increase in Number of Pressure Ulcers

Complete Data Cases: 593 Number of Events: 4 Agency Incidence: 0.7% Reference Incidence: 0.4%

Patient ID	Last Name	First Name	Gender	Birth Date	SOC/ROC	DC/Transfer
315867385	Dodge	Robert	M	12/06/1937	10/29/99	11/09/99
133711082	Koch	Jane	F	11/11/1915	10/20/99	02/14/00
417495912	Beal	Tracy	F	04/07/1914	04/05/00	07/06/00
870032669	Martineau	Lyn	M	12/19/1930	07/24/00	08/03/00

Substantial Decline in 3 or More Activities of Daily Living

Complete Data Cases: 382 Number of Events: 3 Agency Incidence: 0.8% Reference Incidence: 0.5%

Patient ID	Last Name	First Name	Gender	Birth Date	SOC/ROC	DC/Transfer
854314071	Henrich	Byron	M	06/29/1940	04/06/00	08/02/00
424787337	Seals	Flo	F	11/20/1927	02/01/00	02/21/00
500582191	Klebe	Kathleen	F	08/26/1916	01/27/00	04/03/00

Substantial Decline in Management of Oral Medications

Complete Data Cases: 189 Number of Events: 1 Agency Incidence: 0.5% Reference Incidence: 0.5%

Patient ID	Last Name	First Name	Gender	Birth Date	SOC/ROC	DC/Transfer
502513146	Botello	Brenda	F	06/03/1924	05/01/00	08/20/00

Unexpected Nursing Home Admission

Complete Data Cases: 105 Number of Events: 3 Agency Incidence: 2.9% Reference Incidence: 3.9%

Patient ID	Last Name	First Name	Gender	Birth Date	SOC/ROC	DC/Transfer
952821056	Burcham	Nancy	F	09/17/1936	05/30/00	07/08/00
118840231	Elder	Jean	F	01/20/1923	09/06/99	10/15/99
645083076	Condon	Jack	M	04/29/1929	07/20/00	08/05/00

TABLE 3.1: Sample (Tabular) Adverse Event Outcome Report. (cont'd)

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Agency ID: HHA01
Location: Anytown, USA
Medicare Number: 007001
Medicaid Number: 999888001

Requested Current Period: 09/1999-08/2000
Actual Current Period: 09/1999-08/2000
Number of Cases in Current Period: 601
Number of Cases in Reference Sample: 29983
Date Report Printed: 11/30/2000

Adverse Event Outcome Report
Patient Listing

Discharged to the Community Needing Wound Care or Medication Assistance

Complete Data Cases: 401 Number of Events: 4 Agency Incidence: 1.0% Reference Incidence: 0.5%

Patient ID	Last Name	First Name	Gender	Birth Date	SOC/ROC	DC/Transfer
047170580	Jackson	Todd	M	08/22/1917	02/17/00	06/16/00
019528462	Hochman	Chris	M	11/13/1917	04/14/00	07/16/00
197215357	Libiran	Andrew	M	11/05/1937	10/11/99	10/16/99
407160030	Trombley	Mona	F	03/21/1933	04/17/00	07/14/00

Discharged to the Community Needing Toileting Assistance

Complete Data Cases: 407 Number of Events: 2 Agency Incidence: 0.5% Reference Incidence: 0.8%

Patient ID	Last Name	First Name	Gender	Birth Date	SOC/ROC	DC/Transfer
675779542	Egger	Patricia	F	08/22/1915	04/06/00	05/13/00
083773193	Loper	Patrick	M	10/18/1924	03/13/00	04/18/00

Discharged to the Community With Behavioral Problems

Complete Data Cases: 407 Number of Events: 5 Agency Incidence: 1.2% Reference Incidence: 0.8%

Patient ID	**Last Name**	**First Name**	**Gender**	**Birth Date**	**SOC/ROC**	**DC/Transfer**
653640671	Quick	Roseann	F	09/13/1934	10/22/99	11/20/99
251160016	Enkey	John	M	09/22/1940	02/03/00	05/12/00
932752042	Maben.	Sylvia	F	07/23/1915	02/28/00	03/05/00
239777508	Gayle	Diane	F	09/09/1937	05/11/00	07/06/00
511499232	Jones	Ronald	M	12/03/1932	10/15/99	12/03/99

Unexpected Death

Complete Data Cases: 523 Number of Events: 4 Agency Incidence: 0.8% Reference Incidence: 1.1%

Patient ID	Last Name	First Name	Gender	Birth Date	SOC/ROC	DC/Transfer
205640357	Carlson	Rosie	F	09/24/1931	01/02/00	01/03/00
027698081	Niccolucci	Sandy	F	07/13/1922	04/27/00	04/28/00
132486118	Starnes	Isabella	F	03/08/1937	06/08/00	06/17/00
031382376	Trinidad	Ann	F	06/06/1933	05/22/00	08/25/00

C. MEANING OF THE INFORMATION IN THE ADVERSE EVENT REPORT

An adverse event potentially reflects a serious health problem or decline in health status for an individual patient. The word "potentially" is important. For example, look at the event "Emergent Care for Wound Infections, Deteriorating Wound Status." This event is computed from the response to OASIS items M0830 and M0840 at Discharge or Transfer. When an agency investigates this event, they may find situations where the patient appropriately went or was sent to the

TABLE 3.2: Source(s) of Adverse Event Outcome Report Information.

Adverse Event Outcome Report Measures	OASIS-B1 Item(s) and Time Point(s)
Emergent Care for Injury Caused by Fall or Accident at Home	M0830 (Transfer/Discharge) M0840 (Transfer/Discharge)
Emergent Care for Wound Infections, Deteriorating Wound Status	
Emergent Care for Improper Medication Administration, Medication Side Effects	
Emergent Care for Hypo/Hyperglycemia	
Development of Urinary Tract Infection	M0510 (SOC/ROC and Discharge)
Increase in Number of Pressure Ulcers	M0450 (SOC/ROC and Discharge)
Substantial Decline in Three or More Activities in Daily Living	M0280 (SOC/ROC) M0640, M0670, M0680, M0690, M0700 (SOC/ROC and Discharge)
Substantial Decline in Management of Oral Medications	M0780 (SOC/ROC and Discharge)
Unexpected Nursing Home Admission	M0270 (SOC/ROC) M0900 (Transfer/Discharge)
Unexpected Death	M0280 (SOC/ROC) M0100 (Discharge/Transfer/Death)
Discharged to Community Needing Wound Care or Medication Assistance	M0300, M0350, M0460, M0488, M0570, M0780, M0870 (Discharge)
Discharged to Community Needing Toileting Assistance	M0350, M0680, M0700, M0870 (Discharge)
Discharged to Community with Behavioral Problems	M0350, M0610, M0870 (Discharge)

emergency room or physician's office at the very first sign of deteriorating wound status. This would be an example of appropriate care. However, the agency may also find situations where a wound's status was getting worse and worse and worse over the period of several visits -- and the responsible clinician was not responding in any way to this deterioration in status. This would be determined to be inadequate care, and in this case the adverse event indicates a problem in patient care.

Whether or not the care for a patient listed on the tabular adverse event outcome report was problematic cannot be known until the agency actually investigates the care provided. Guidance on conducting an investigation of care provided is detailed in Section 4 of this manual.

SECTION 4

USING REPORTS FOR THE OUTCOME-BASED QUALITY MONITORING PROCESS

A. OVERVIEW

Once an agency obtains its case mix and adverse event outcome reports, the staff can begin the outcome-based quality monitoring (OBQM) process. The report information allows the HHA to investigate specific outcomes (from the adverse event outcome report) to determine where changes in care provision are indicated. We encourage agencies to investigate each of the adverse event outcomes presented in the report, as each event represents a potential problem in care delivery. The precise sequence in which an agency investigates these outcomes is influenced by its case mix report as well as the incidence of specific adverse event outcomes. If changes in care provision are indicated from this investigation, an improvement plan can be developed, implemented, and monitored over time to determine whether the desired changes are being consistently performed by agency clinical staff. Subsequent adverse event outcome reports will provide feedback to the agency on the success of these efforts.

B. STEPS IN THE QUALITY MONITORING PROCESS TO FOLLOW WITH THE ADVERSE EVENT OUTCOME REPORTS

The sequence of steps to follow in this quality monitoring process is:

- review each report briefly to obtain an overall sense of the content;
- review the case mix report in more detail;
- from this review, prioritize the potential adverse event outcomes to investigate first;
- review the care provided to patients listed in the tabular adverse event outcome report;
- identify instances of problematic care provision; draw conclusions about aspects of care delivery that will need change or modification;
- develop an improvement plan that incorporates necessary changes in care delivery;
- implement the plan in the agency;

- monitor the plan after implementation; and
- review the subsequent adverse event outcome reports to determine whether the results of the care delivery have changed the incidence of the adverse events in the agency.

Each of these steps is discussed in more detail in the remainder of this section. As examples, we will utilize the case mix and adverse event outcome reports for Faircare Home Health Services for the report period of September 1999 through August 2000, (refer to Tables 2.1, 3.1, and 3.2, and Figure 3.1).

1. Big Picture Review

Review your agency's case mix report and graphical adverse event outcome report to obtain an overall sense of the content. This review should be brief and done in an "overview" manner to obtain a broad sense of the contents. Use the G*uidelines for Reviewing the Case Mix and Adverse Event Outcome Reports* (found in the Appendix of this manual) for the review of each report.

2. Detailed Case Mix Report Review

Conduct an in-depth review of the case mix report. This detailed review examines the types of patients for whom your agency is providing care, their characteristics at the start of a care episode, and their average length of stay. Such a review provides an opportunity to verify (or not) the accuracy of your perceptions of your agency's caseload. If you discover your perceptions are extremely different from the picture of your patients presented in the case mix report, data accuracy problems may exist with your agency's OASIS data. Keep this possibility in mind as you proceed with your review.

A large reference sample provides the comparison for your agency's patients in these reports. Because a large sample size increases the likelihood of statistically significant differences being found between your agency and the reference group, you will not want to limit your review of the case mix report to only those factors with statistically significant differences. There are additional considerations to bear in mind, which we highlight in this section. The following points are helpful in evaluating the various sections of the report.

a. *What is my patients' average age?* Is this higher than, lower than, or about the same as the reference group? If there is a difference, is it statistically significant? Refer to Faircare's case mix report. Note that Faircare's patients are younger than the reference group to a statistically significant extent.

b. *Scan the payment source, current living situation, assisting persons' information, and primary caregiver assistance.* The comparison with the reference group may or may not be meaningful to examine more closely; most agencies simply are interested in the raw data percentages of their own patients that fall into the various categories.

c. *Look at the location of your patients 14 days prior to SOC/ROC.* Do you tend to have more referrals from specific types of inpatient facilities? Note that Faircare's patients were not particularly different from the reference sample in these areas.

d. *Review your patients' overall prognoses at the start of the episodes*. This is one area where you may begin to infer your patients' overall acuity level. Faircare's patients are similar to those in the reference group in respect to recovery from illness, but fewer had a good rehab prognosis.

e. *Assess your patients' overall functional status at SOC/ROC and prior to SOC/ROC, for both Activities of Daily Living (ADLs) and Instrumental Activities of Daily Living (IADLs).* Look especially for highly significant differences between your patients and those in the reference group and determine whether those differences show your patients to be generally more impaired, generally less impaired, or possessing a mixed pattern of sometimes more impairments and sometimes less. In ADLs, Faircare's patients were significantly more impaired in grooming at SOC/ROC (and prior to SOC/ROC), but significantly less impaired in transferring at those same time points. In IADLs, Faircare's patients showed a pattern of being significantly more impaired.

f. *Review various aspects of your patients' health status, such as respiratory status, sensory status, pain, and therapies being received at home.* Note that Faircare's patients are very similar to the reference group in nearly all these areas except one (Faircare's patients are slightly less impaired in hearing).

g. *Examine aspects of your patients' neurologic/emotional/behavioral health status*. Faircare has a higher percentage of its patients with a severe anxiety level and a much larger percentage with behavior problems more than twice a week.

h. *Review the presence of integumentary status problems*. Faircare has a higher percentage of patients with pressure ulcers and a much larger percentage with Stage 3-4 pressure ulcers.

i. *Consider elimination status as you examine your patients' health status*. Note that Faircare has a lower percentage of patients with urinary incontinence or catheters present, but a larger percentage with UTIs within the past 14 days.

j. *Examine the percentage of patients with acute or chronic conditions*. Note the highest frequencies within the agency in addition to the presence of significant differences from the reference group. For example, Faircare's most frequent acute condition is that of open wounds/lesions, followed by cardiac/peripheral vascular conditions. Faircare's most frequent chronic condition is that of dependence in medication administration, followed by dependence in living skills, and dependence in personal care. Faircare is most significantly different from the reference group in its percentage of patients with contagious/ communicable conditions, acute mental/emotional conditions, chronic dependence in personal care, and in the percentage of chronic patients who have caregivers present.

DATA QUALITY ALERT:

A high percentage of patients with contagious/communicable conditions should serve as a "red flag" of potential data quality problems to an agency. If an agency is surprised at the large percentage of its patients with contagious/communicable conditions, it is appropriate to check the ICD codes that have been entered into OASIS, particularly as responses to M0190 or M0210. If two-digit surgical procedure codes are erroneously entered in response to these items, they may be recognized by the data entry software as three-digit codes signifying contagious/communicable diseases (if data entry staff mistakenly enter a leading zero). An erroneously large number of patients are thus coded as having contagious/communicable diseases. (An example of this problem is the two-digit surgical procedure code for joint repair, 81, erroneously recorded in response to M0190; if this is entered as 081, the data transmitted to the State system will reflect the medical diagnosis of "other typhus," which is an uncommon home care diagnosis.) Agencies with a statistically significantly large percentage of patients with contagious/communicable diseases thus are advised to investigate further for the possible presence of this type of error.

k. *Evaluate the highest frequency of diagnoses for which patients are receiving home care*. Note that Faircare has some areas where these diagnoses are significantly different from the reference group, including infectious/parasitic disease (another sign of the potential data accuracy

problems described above), mental diseases, nervous system diseases, and other injuries.

l. *Review your agency's average length of stay (LOS) to discharge (or transfer to an inpatient facility).* Faircare's LOS is significantly longer than the LOS for the reference sample.

3. Prioritize Adverse Event Outcomes for Investigation

Next, proceed to the graphic adverse event outcome report. Using overall impressions of your agency's patients gathered from the case mix report, select those adverse event outcome(s) most relevant to your agency.

High-priority adverse event outcomes are: (a) those with the most clinical relevance to the agency, and (b) those with the highest incidence as compared to the reference group. An "ideal" adverse event outcome for early investigation will meet both of these criteria.

Using Faircare as an example, three adverse event outcomes stand out as high priority for investigation. Remember that approximately one-third of Faircare's patients had open wounds/lesions (the most frequently occurring acute condition). The adverse event outcome report shows a higher percentage of Faircare's patients than the reference group receiving Emergent Care for Wound Infections or Deteriorating Wound Status. A higher percentage of Faircare's patients also were Discharged to the Community Needing Wound Care or Medication Assistance. (These two patient problems are reported in a single adverse event outcome. Should the patients need medication assistance rather than wound care, remember that Faircare also had a high percentage of patients with chronic dependence in medication administration.)

Faircare also had a significantly higher percentage of patients with pressure ulcers at SOC (or ROC), yet had a larger rate of Increase in the Number of Pressure Ulcers than the reference group. Any of these three adverse event outcomes are particularly relevant for Faircare as a priority for further investigation.

Two other adverse events appear to be potential high priority candidates. Though Faircare had a significantly larger percentage of patients with UTIs at SOC/ROC, it also had a large number of patients who Developed UTIs during the care episode. Another possible candidate for early investigation is the adverse event of Discharged to the Community with Behavioral Problems, given Faircare's high percentage of patients with behavioral problems more than twice a week.

From this review, at least five adverse event outcomes rank high on Faircare's prioritized list as most important to investigate first. Your agency also can prepare such a list of adverse event outcomes (based on the characteristics of your patients) that are most relevant to your agency.

4. Identify Patients Experiencing the Selected Adverse Event Outcome

Once a specific adverse event outcome has been selected, refer to the tabular version of the adverse event outcome report to know which patients experienced the adverse event during the course of their care episode.

5. Select Cases to Investigate

Decide whether the episodes of care for all patients who experienced the adverse event, as listed in the tabular report, should be investigated or only a sample used. Agencies with a very large total caseload may find 100 or more patients listed, though the percentage of patients experiencing an adverse event may be two percent or fewer. Obviously the detailed investigation of 100 or more episodes of care is a very burdensome activity. In this situation agencies should sample from the listed cases. We suggest that an adverse event outcome investigation include at least 20 cases if more than 30 are represented in the total listing. Agencies such as Faircare with fewer than 30 cases listed for each adverse event should include every case in their investigation.

6. Review Clinical Records for Cases Selected

Using the SOC (or ROC) and the discharge (or transfer) dates listed in the report, review the clinical records of the listed patients.

a. Determine the Portion of an Episode to Review: Depending on the specific adverse event, the entire episode of care need not always be reviewed. For those events described as Emergent Care for ..., the specific instance(s) of emergent care will need to be located in the episode. The care review then should address at least a few visits that occurred prior to the emergent care. Other events should be investigated near the time of discharge from the agency (Unexpected Death, Unexpected Nursing Home Admission, and Discharged to the Community Needing...). The remaining adverse event outcomes (Development of a Urinary Tract Infection, Increase in Number of Pressure Ulcers, Substantial Decline in 3 or More Activities of Daily Living, and Substantial Decline in Management of Oral Medications) are most likely to require a closer review of the entire care episode.

b. Develop a Chart Audit Tool: When reviews are performed by more than one individual in the agency, the total number of reviews can be done quickly, and the implications for overall care provision can be determined sooner.

However, multiple reviewers also increase the likelihood of inconsistency between the reviews. The development of a chart audit tool may be something to consider. An objective and specific chart audit tool decreases the potential for inconsistency between reviewers.

To develop such an audit tool, agency clinical staff can be asked to quickly list several clinical actions that would avoid the occurrence of the adverse events. These clinical actions can be compiled into the chart audit tool used for this review. Because it is suggested that the adverse event outcomes be investigated in their entirety over the course of several months, the chart audit tools can be refined and reused in response to future adverse event outcome reports. The audit tool also facilitates tallying findings from the reviews, which assists to formulate conclusions, even in those cases where one person conducts all the reviews.

c. Identify the Appropriateness of Care Provision: In reviewing the patient care provided, your agency investigative team should keep in mind the definition of adverse events as occurrences that potentially reflect a serious health problem or problem in quality of care for an individual patient. In the investigation of care, the team is likely to discover some instances of highly appropriate care and some instances where care might have been improved. For example, if Faircare's Quality Improvement (QI) Team begins an investigation of the adverse event outcome Emergent Care for Wound Infections, Deteriorating Wound Status, it would review all 15 instances where patients received such emergent care. It is very possible that in some of those instances, the QI Team will discover patients being sent to the emergency room at the very first signs of deteriorating wound status. The team would consider this to be very appropriate care. In other instances, however, there may have been signs or symptoms of deteriorating wound status over several visits with no communication with the physician or no apparent recognition (on the part of the responsible clinician) of this deteriorating status. Faircare's QI team would undoubtedly regard this as evidence of inadequate care.

d. Summarize the Clinical Record Review: The conclusions derived from the clinical record review are summarized as an important document for use in the agency's total quality monitoring program. We strongly suggest that a summary include both instances of highly appropriate care provision and instances of problems in care provision. Such a summary of highly appropriate care provision is ideal to share with clinical staff as a powerful reinforcement of the worth of accurate OASIS data collection and the meaningful utility of the adverse event outcome report. Such an opportunity should not be missed!

When problems in care provision are noted, your summarization will lead to the development of an improvement plan. The elements of such a plan are described in the next section.

7. Develop An Improvement Plan

Your agency will want to take steps to improve care in those areas where inadequate or problematic care provision is noted. This is best done through development of an improvement plan. Such a plan should include the following components:

a. Statement of the Problem: A clear identification of the problem in terms of patient care delivery is necessary. Examples of specific problem statements are: patient teaching does not emphasize the signs and symptoms of wound infection, patient teaching does not include appropriate indications for when to call the home care nurse for questions about wound status, patient's understanding of information taught was not evaluated during first two weeks of care, etc.

b. List of New Care Practices: State the care practices expected to occur in the future. What are clinicians expected to do when they encounter patients with similar care problems/issues from now on? These statements also should be clearly stated expectations, e.g., patients with wounds should be instructed to follow a specific procedure for questions about their wound, etc.

c. Delineation of Implementation Process: Implementation allows the plan to move from paper to reality. You can facilitate this process with a clear delineation of implementation steps and appropriate delegation of responsibility/authority, e.g., the current teaching tool for use with wound patients will be revised to include a procedure for determining whom to call about wound concerns. (Additional discussion of implementation approaches most effective in changing clinical care delivery can be found in Supplement A.)

d. Mechanism for Monitoring New Care Practices: Identify ways to monitor the staff's use of new (or revised) care practices. Because home health care providers practice autonomously, modifying care practices is sometimes more challenging than in other clinical settings. Agency management staff should not simply "assume" that suggested practice modifications will necessarily occur. A monitoring approach might include the use of the chart audit tool to review records of discharged patients at specific intervals. If the monitoring activity involves clinical record review, this often can be incorporated into other chart review activities and completed in a few additional minutes.

A designation of the appropriate individual(s) or group within the agency to conduct the monitoring activities. A plan also identifies who will compile the

results of the monitoring activities, when these results will be reviewed, and by whom. If clinical care delivery is not changing as desired, who will know this situation and when? This is important feedback for the group who puts the improvement plan into place.

8. Implement the Improvement Plan as Designed

The plan itself includes all the necessary steps to follow, but it must be actually put into place for expected change to occur. This is comparable to making a resolution a reality.

9. Determine Effectiveness of the Improvement Plan

Determine whether the modification of clinical care practices has made a difference by examining the next adverse event outcome report. When the next adverse event outcome report is received (assuming that the incidence of the adverse event outcome under consideration is not zero), it will be necessary to review the incidents (or a sample of the incidents) reported. As you prepare for this review, remember that not every adverse event outcome represents a problem in care delivery. Some events may reveal the presence of appropriate care. Therefore, it is unlikely for the incidence of any of these events to drop to zero, even with the implementation of more effective care practices. This perspective will help agency staff be realistic in their expectations of what the subsequent reports may look like.

We encourage home health agencies to investigate all the adverse events appearing in the adverse event outcome report, but this investigation can proceed in phases. The approach discussed in this section involves prioritizing outcome events for investigation. Once you have determined the priority order, the investigation can be integrated into your agency's routine quality program. This is the overall goal -- to incorporate the monitoring of adverse event outcomes as part of an ongoing quality program.

C. SUMMARY

The use of the adverse event outcome and case mix reports to monitor the quality of care provided to home care patients represents the use of OASIS data for information beyond that of patient status. From these reports, clinical staff become aware of the variety of information available from OASIS data and are likely to look forward to various reports that will be made available. There is an increased understanding of the need for overall data accuracy within the agency. Quality improvement staff should be aware of this emphasis and expect to incorporate additional discussions of OASIS data quality into staff meetings, newsletters, bulletin boards, and other methods of agency communication.

These reports and the related investigation of care processes help agencies move beyond "hunches" in evaluating quality of patient care. Now you are able to expand quality monitoring programs to incorporate an examination of the effects of care on patients. These reports represent an important first step in truly using outcome data for quality improvement.

SUPPLEMENT A TO SECTION 4

CHANGING CLINICAL PRACTICE

Modifying clinicians' care practices to incorporate interventions that are more effective has been studied in many health care settings. The challenges are probably higher in home care than in most other settings, given the autonomous nature of the practice site and considering that clinicians of varying disciplines provide care. Nonetheless, certain key factors have been identified as contributing to success in modifying care delivery.

Does the staff know what the change is? While seemingly obvious as an essential ingredient, this aspect of practice change is sometimes overlooked. This step needs to involve some type of educational component, whether formally or informally presented. Care processes should not be expected to change without the clinicians being informed of why the change is needed, what the new care processes are, and the rationale for the processes being selected for implementation. Periodic repetition of the information is also important to acknowledge and plan.

Has the necessary knowledge/skill (of the new process) been conveyed? Again, apparently an obvious step, but not always well implemented. This step also involves an educational and practice component. If performance of a procedure is involved, a return demonstration should be required. Make the educational experience brief but to the point (and fun).

Do organizational processes allow the change to occur? An extremely important step that acknowledges the reality that simply "telling" clinicians to change behavior is unlikely to produce the desired result. System modification is necessary for most process change to be fully implemented, and this is true of care delivery as well as other processes. Those responsible for planning and implementing new or modified approaches to care delivery also should be responsible for the review and possible modification of internal agency processes that support care delivery change. For example, this may include making new equipment available or modifying documentation that incorporates reminders of new processes or other similar internal system modifications.

SECTION 5

ROLE OF THESE REPORTS IN THE AGENCY'S OVERALL QUALITY PROGRAM

The Conditions of Participation for Medicare-certified home health agencies at §484.52 require an overall evaluation of the agency's total program at least annually and clinical record review at least quarterly. Patient care services are identified as one component of the agency's total program that must be included in this evaluation. The use of the case mix and adverse event outcome reports to review and improve patient care delivery is congruent with these program evaluation components.

It is also anticipated that State survey agencies will incorporate the adverse event outcome reports into their pre-survey preparation (off-site) as well as onsite during the actual survey. Specific adverse event outcomes and their potential incorporation in the survey process are included in this section.

A. CURRENT REGULATORY REQUIREMENTS

Condition of Participation: Evaluation of the Agency's Program - §484.52

The HHA has written policies requiring an overall evaluation of the agency's total program at least once each year by a group of professional advisory personnel (or a committee of this group), HHA staff, and consumers, or by professional individuals outside the agency working in conjunction with consumers. The evaluation consists of an overall policy and administrative review and a clinical record review. The evaluation assesses the extent to which the agency's program is appropriate, adequate, effective, and efficient. Results of the evaluation are reported to and acted upon by those responsible for the operation of the agency and are maintained separately as administrative records.

1. Standard: Policy and Administrative Review - §484.52(a)

   As part of the evaluation process, the policies and administrative practices of the agency are reviewed to determine the extent to which they promote patient care that is appropriate, adequate, effective, and efficient. Mechanisms are established in writing for the collection of pertinent data to assist in evaluation.

2. Standard: Clinical Record Review - §484.52(b)

   At least quarterly, appropriate health professionals, representing at least the scope of the program, review a sample of both active and closed clinical records to determine whether established policies are followed in furnishing

services directly or under arrangement. There is a continuing review of clinical records for each 60-day period that a patient receives home health services to determine adequacy of the plan of care and appropriateness of continuation of care.

B. USING ADVERSE EVENT OUTCOME REPORTS TO ADDRESS THE REGULATORY REQUIREMENTS

In Standard §484.52(a), the agency is expected to have in place policies and administrative practices to promote patient care that is appropriate, adequate, effective, and efficient. Further, it is noted that mechanisms are established in writing for the collection of pertinent data to assist in evaluation.

The investigation of adverse event outcomes provides evidence of the agency's review of potential problems in care provision (the defining characteristic of adverse event outcomes). If problems in care provision are discovered, the development and implementation of the improvement plan demonstrates the agency's goal(s) of overcoming or minimizing existing problems. The use of a chart audit tool for the adverse event outcome investigation provides evidence of the collection of pertinent data to assist in evaluating patient care.

In utilizing the adverse event outcome investigation to (partially) address this standard, the HHA in its policies and administrative practices should identify the way(s) in which this investigation contributes to the ongoing monitoring of patient care. The agency policies and procedures must address how the reports are incorporated into the program evaluation. Summaries of the adverse event investigation findings also can be included in the description of this overall evaluation process.

In Standard §484.52(b), a quarterly record review is required to determine whether established agency policies are being followed in the provision of care. Two aspects of the adverse event outcome report investigation address this standard. It is expected that the chart audit tool used to investigate the adverse event outcome(s) will incorporate any relevant agency policies for care provision. The monitoring of clinician compliance with new (or revised) care practices likewise should incorporate relevant agency policies. When the investigation process is conducted in a phased manner, as presented in Section 4, the adverse events can be investigated and monitored on a quarterly basis. In this way, the associated record review is incorporated into an agency's current quality monitoring requirements.

The investigation of adverse event outcomes described in Section 4 thus becomes part of the agency's overall quality monitoring program. While these reports represent many agencies' first exposure to the use of outcomes for

quality improvement activities, the utility of the reports for the agency's overall quality monitoring program is clear. The benefit to patients is also evident as agencies focus on continuously improving the quality of care they provide. These early steps in outcome-focused quality improvement will lay the foundation for the agency-level activities to be conducted in response to the risk-adjusted outcome reports expected next year.

C. USING ADVERSE EVENT OUTCOME REPORTS IN THE SURVEY PROCESS

State survey agencies as well as HHAs will have access to the adverse event outcome reports. State survey agencies will review available reports prior to going onsite as part of their pre-survey preparation. The reports may assist them to identify areas of focus during the onsite survey.

In addition, surveyors will also conduct onsite review during the actual survey. Surveyors will expect HHAs to be using the information in the reports to improve their patient outcomes. Surveyors will review the HHA's response to its own reports; that is, the agency's use of the reports for quality monitoring will be assessed. Those reviews of clinical practices, policies, and procedures will be of particular interest to surveyors, including how the agency addresses any systemic issues that may be present in an effort to reduce the incidence of similar adverse events in the future.

For example, surveyors may review the specific patient situations included in the adverse event outcome reports to determine whether any events might have been prevented. Another focus of the surveyor's review may be to determine whether any of the adverse event outcomes was due to non-compliance with the Conditions of Participation on the part of the HHA.

Table 5.1 presents examples of adverse event outcomes and actions the surveyor may take as part of his/her investigation during a survey.

TABLE 5.1: Example Adverse Event Outcomes and Possible Surveyor Action.

Adverse Event Outcome	Possible Surveyor Action and Relationship to Conditions of Participation
1. Emergent care for wound infections, deteriorating wound status.	Surveyors can review the comprehensive assessment and plan of care to see if any additional action on the part of the HHA might have prevented an emergency room visit or prevented wound deterioration. Was the patient's wound evaluated during the visits? Was the physician notified promptly of any changes in wound status that suggested a need to alter the plan of care? This relates to the plan of care requirements at 42 CFR 484.18(b).
2. Emergent care for improper medication administration, medication side effects.	Surveyors can determine if the HHA complied with the requirements included as part of the comprehensive assessment at 42 CFR 484.55 (c). Did the HHA include a review of all medications the patient was using to identify potential adverse effects and drug reactions, ineffective drug therapy, significant side effects, significant drug interactions, duplicate drug therapy, and noncompliance with drug therapy?
3. Substantial decline in management of oral medications.	Surveyors can review the comprehensive assessment, plan of care, and visit notes to determine when or if the HHA identified the patient's decline in managing his/her medications and what steps, if any, the HHA took to address the situation. Did the HHA notify the physician of the need to alter the plan of care? This relates to the requirement at 42 CFR 484.18.
4. Emergent care for injury caused by fall or accident at home.	Surveyors may review the comprehensive assessment to determine if any identified safety hazards were discussed with the patient and to review if the plan of care included any safety measures necessary to protect against injury, as required by 42 CFR 484.18. Surveyors will also review the patient's condition, diagnosis, medications, and plan of care to identify whether the HHA used the comprehensive assessment to make sound care planning decisions appropriate to the patient's needs.

TABLE 5.1: Example Adverse Event Outcomes and Possible Surveyor Action. (cont'd.)

Adverse Event Outcome	Possible Surveyor Action and Relationship to Conditions of Participation
5. Substantial decline in three or more activities of daily living.	Surveyors can review the initial assessment and ongoing clinical notes to determine if the patient's functional abilities had declined in relation to the specific care planned and provided by the HHA. If the patient's clinical and functional abilities did not progress, surveyors will review if intervening actions were instituted and recorded appropriately. Surveyors may review the coordination between staff to see if their efforts were coordinated effectively to support the objectives outlined in the plan of care, as required by 42 CFR 484.14(g).

The case mix and adverse event outcome reports thus can be used by both HHA and by the State survey agency to assess the quality of care provided to an HHA's patients. Agencies are strongly encouraged to take advantage of the information presented in the reports for their ongoing quality-monitoring program.